



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2015-0688; FRL-10018-27]

### **Agency Information Collection Activities; Proposed Renewal of an Existing Collection and Request for Comment; Recordkeeping and Reporting Requirements for Allegations of Significant Adverse Reactions to Human Health or the Environment.**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (PRA), this document announces that EPA is planning to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). The ICR, entitled: “Recordkeeping and Reporting Requirements for Allegations of Significant Adverse Reactions to Human Health or the Environment” and identified by EPA ICR No. 1031.12 and OMB Control No. 2070-0017, represents the renewal of an existing ICR that is scheduled to expire on October 31, 2021. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

**DATES:** Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2015-0688, by using the *Federal eRulemaking Portal* at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to

provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Thomas Forbes (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 566-0810; email address: [forbes.thomas@epa.gov](mailto:forbes.thomas@epa.gov).

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. What Information is EPA Particularly Interested in?**

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.
2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
3. Enhance the quality, utility, and clarity of the information to be collected.
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

### **II. What Information Collection Activity or ICR Does this Action Apply to?**

*Title:* Recordkeeping and Reporting Requirements for Allegations of Significant Adverse Reactions to Human Health or the Environment.

*ICR number:* EPA ICR No. 1031.12.

*OMB control number:* OMB Control No. 2070-0017.

*ICR status:* This ICR is currently scheduled to expire on October 31, 2021. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the *Federal Register* when approved, are listed in 40 CFR part 9, are displayed either by publication in the *Federal Register* or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

*Abstract:* TSCA section 8(c) requires companies that manufacture, process, or distribute chemicals to maintain records of significant adverse reactions to health or the environment alleged to have been caused by such chemicals. Since section 8(c) includes no automatic reporting provision, EPA can obtain and use the information contained in company files only by inspecting those files or requiring reporting of records that relate to specific substances of concern. Therefore, under certain conditions, and using the provisions found in 40 CFR part 717, EPA may require companies to report such allegations to the Agency. EPA uses such information on a case specific basis to corroborate suspected adverse health or environmental effects of chemicals already under review by EPA. The information is also useful to identify trends of adverse effects across the industry that may not be apparent to any one chemical company. This ICR addresses the information reporting and recordkeeping requirements found in 40 CFR part 717.

Responses to the collection of information are mandatory (see 40 CFR part 717). Respondents may claim all or part of a notice as CBI. EPA will disclose information that is

covered by a CBI claim only to the extent permitted by, and in accordance with, the procedures in 40 CFR part 2.

*Burden statement:* The annual public reporting and recordkeeping burden for this collection of information is estimated to average 8 hours per report. Burden is defined in 5 CFR 1320.3(b).

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

*Respondents/Affected Entities:* Entities potentially affected by this ICR are companies that manufacture, process, import, or distribute in commerce chemical substances or mixtures.

*Estimated total number of potential respondents:* 13,160.

*Frequency of response:* On occasion.

*Estimated total average number of responses for each respondent:* 1.4.

*Estimated total annual burden hours:* 25,527 hours.

*Estimated total annual costs:* 1,987,487.00

### **III. Are There Changes in the Estimates from the Last Approval?**

There is an increase in the total cost associated with this ICR as a result in an increase in the wage rate from \$1,911,477 to \$1,987,487. This change is an adjustment.

In addition, OMB has requested that EPA move towards using the 18-question format for ICR Supporting Statements used by other federal agencies and departments and is based on the submission instructions established by OMB in 1995, replacing the alternate format developed by EPA and OMB prior to 1995. EPA intends to update this Supporting Statement during the comment period to reflect the 18-question format, and has included the questions in an attachment to this Supporting Statement. In doing so, the Agency does not expect the change in format to result in substantive changes to the information collection activities or related estimated burden and costs.

#### **IV. What is the Next Step in the Process for this ICR?**

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

**Authority:** 44 U.S.C. 3501 *et seq.*

Dated: March 18, 2021.

**Michal Freedhoff,**

*Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

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